



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,329	07/18/2003	Toshihiro Mori	2870-0260P	2530
2292 7590 07/27/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 07/27/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p align="center">10/621,329</p>	<p>Applicant(s)</p> <p align="center">MORI ET AL.</p>	
	<p>Examiner</p> <p align="center">Christopher M. Babic</p>	<p>Art Unit</p> <p align="center">1637</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1, 2, and 4-8, and 10-18 are pending. The following Office Action is in response to Applicant's response dated May 10, 2007.

### ***Claim Objections***

Claim(s) 7 and 8 are objected to because of the following informalities: The claims are dependent on a canceled claim (e.g. 2). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 - Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim(s) 8 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

The specification has not taught how to make or use a non-porous surface saponified cellulose acetate membrane within the methods as required by claim 7. Cellulose acetate membranes, inherently, are porous membranes. The specification does not provide any working examples of non-porous cellulose acetate membranes. Furthermore, the state of the art suggests that porous membranes are traditionally used for the isolation of nucleic acid (see the applied art below). It would require inventive and undue experimentation in order to determine how to provide such a non-porous surface saponified cellulose acetate membrane for the practice of the claimed invention since none are known to exist. Therefore, it is concluded that it would require undue experimentation to practice the claimed invention.

#### **Response to Arguments**

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the specification clearly describes that non-porous acetyl cellulose membranes will work in the present invention. Applicant further argues that Mullis does not indicate that only porous membranes can be used within methods of adsorbing and desorbing nucleic acid. These arguments are not persuasive because Applicant has provided no **evidence**, contrary to the prior art, that a non-porous acetyl cellulose membrane would function within the claimed inventions. Mullis expressly states that, "...it is believed that high molecular weight DNA released by gentle lysis of cells is **trapped** on the porous filter by virtue of the fact that the DNA chains are considerably longer than the inter-pore distance on the surface of the filter such that separate regions

Art Unit: 1637

of a single high molecular weight DNA chain may be simultaneously drawn into different pores, thus preventing complete passage of the molecule through either pore.

Accordingly, the high molecular weight DNA molecule is effectively trapped on and/or in the filter col. 6, lines 20-40)." Thus, since DNA does not become immobilized or bound to the acetyl cellulose membrane, it stands to reason that a membrane having NO pores would be unable to trap such macromolecules as DNA. The pores are clearly the structural feature that allows such an acetyl cellulose membrane to isolate macromolecules such as DNA. Furthermore, the Examiner can find no teaching in the prior art that would suggest that a truly NON-POROUS cellulose membrane would be capable of trapping DNA.

Thus, the rejection is maintained.

***Maintained Grounds of Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1637

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1. Claim(s) 1, 2, 7, 9, 12, and 14-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis (U.S. 5,187,083) as evidenced by GE Osmonics (<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes") in view of Bryk et al. ("Porous structure of cellulose acetate ultrafiltration membranes of various degrees of saponification" *Polymer Science U.S.S.R.*, Volume 32, Issue 7, 1990, Pages 1401-1409).**

Regarding claim 1, Mullis teaches a method for separating and purifying a nucleic acid from a biological sample comprising the step of: adsorbing and desorbing a nucleic acid to and from a membrane of an organic macromolecule (col. 10, ex. 4, for example). Specifically, Mullis teaches the capture and elution of DNA from blood on cellulose acetate membrane filters (col. 10, lines 20-30, for example). The membrane referenced in example 4 of Mullis is a 0.45 micron, 2.5 cm diameter, from MSI, Inc. (col. 10, lines 20-25, for example). It is submitted that MSI, Inc. is a division of GE Osmonics (see printout of <http://www.tcn.zaq.ne.jp/membrane/english/MembManufE.htm>, "Websites of Membrane Manufacturers", pg. 5, for example). Ge Osmonics provides cellulose acetate membrane of 0.45 micron, 2.5 cm diameter, and a **thickness of 65-110  $\mu$ m** (see printout of

Art Unit: 1637

<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes", pg. 4, for example). It is submitted that the cellulose acetate membranes taught by Mullis are necessarily within the thickness of 10-500  $\mu\text{m}$  as required by the claimed invention.

Regarding claim 2, a cellulose acetate necessarily has a degree of hydroxyl groups on the surface thereof.

Regarding claim 7, Mullis teaches porous cellulose acetate membranes (col. 5, lines 35-50, for example).

Regarding claim 9, Mullis teaches nucleic acid a sample solution (col. 10, ex. 4, for example).

Regarding claim 12, Mullis teaches washing the membrane with a nucleic acid washing buffer after adsorbing and then desorbing the nucleic acid from the membrane with a solution capable of desorbing the nucleic acid from the membrane (ex. 3, for example).

Regarding claim 14, the desorbing solution has a salt concentration of 0.5 M or less (ex. 3, for example).

With regard to claims 15 and 16, Mullis teaches a method wherein adsorption and desorption of the nucleic acid is performed by use of a unit for isolation and purification comprising (a) a membrane of the organic macromolecule; (b) a container having at least two openings and containing the membrane; and (c) a differential pressure generator connected to one opening of the container. Specifically, Mullis teaches an example wherein the adsorption and desorption of the nucleic acid is

Art Unit: 1637

performed within a vacuum-filtration device which is a container with at least two openings and which contained a cellulose acetate membrane filter (ex. 4, for example). Further, the vacuum filtration device inherently would be connected to a differential pressure generator (i.e. the vacuum) that is connected to an opening of the device.

Mullis does not expressly teach surface saponification of cellulose acetate membranes.

Bryk provides a supporting disclosure that teaches of the effects of saponification on cellulose acetate membranes (abstract; pgs. 1408-1409, for example). They expressly teach that upon saponification of cellulose acetate membranes, among other physical changes, the rigidity of the membrane increases (pg. 1408, para. 3-end; pg. 1409, for example).

It would have been *prima facie* obvious for a practitioner of ordinary skill in the art at the time of invention to apply saponification procedures to the membranes taught by Mullis to increase the membrane rigidity therefore decreasing the likelihood of physical degradation of the membrane, thus arriving at the claimed invention.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not persuasive. Applicant first argues that Bryk does not mention separating and purifying nucleic acid. This argument is not persuasive because Mullis teaches the separation and purification of nucleic acid through the use of cellulose acetate membranes. Furthermore, one cannot show nonobviousness by attacking references individually where the rejections



Art Unit: 1637

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant next argues that Bryk suggests saponified cellulose acetate membranes as less effective as ultrafiltration membranes due to the increase in rigidity, and the corresponding decrease in the ability of the material to mix with a solvent that was observed in the study. This argument is not persuasive because, as set forth above, an increase in the membrane rigidity decreases the likelihood of physical degradation of the membrane during ultrafiltration. It is noted that in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006), the court addressed the "teaching, suggestion, or motivation test" reciting the following,

"Our suggestion test is in actuality quite flexible and not only permits, but **requires**, consideration of common knowledge and common sense,...,Indeed, we have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references **even absent** any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him **capable** of combining the prior art references,...,Persons of varying degrees of skill not only possess varying bases of knowledge, they also possess varying levels of **imagination and ingenuity** in the relevant field, particularly with respect to problem-solving abilities."

A skilled artisan at the time of invention would have seen the benefit of strengthening filtration membranes to resist physical damage.

Thus, the rejections are maintained.

**2. Claim(s) 1, 2, 4-7, 9, 12, and 14-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis (U.S. 5,187,083) as evidenced by GE Osmonics (<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes") in view of Tuccelli et al. (U.S. 5,522,991).**

Regarding claim 1, Mullis teaches a method for separating and purifying a nucleic acid from a biological sample comprising the step of: adsorbing and desorbing a nucleic acid to and from a membrane of an organic macromolecule (col. 10, ex. 4, for example). Specifically, Mullis teaches the capture and elution of DNA from blood on cellulose acetate membrane filters (col. 10, lines 20-30, for example). The membrane referenced in example 4 of Mullis is a 0.45 micron, 2.5 cm diameter, from MSI, Inc. (col. 10, lines 20-25, for example). It is submitted that MSI, Inc. is a division of GE Osmonics (see printout of <http://www.tcn.zaq.ne.jp/membrane/english/MembManufE.htm>, "Websites of Membrane Manufacturers", pg. 5, for example). Ge Osmonics provides cellulose acetate membrane of 0.45 micron, 2.5 cm diameter, and a **thickness of 65-110  $\mu$ m** (see printout of <http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes", pg. 4, for example). It is submitted that the cellulose acetate membranes taught by Mullis are necessarily within the thickness of 10-500  $\mu$ m as required by the claimed invention.

Regarding claim 9, Mullis teaches nucleic acid a sample solution (col. 10, ex. 4, for example).

Regarding claim 12, Mullis teaches washing the membrane with a nucleic acid washing buffer after adsorbing and then desorbing the nucleic acid from the membrane with a solution capable of desorbing the nucleic acid from the membrane (ex. 3, for example).

Regarding claim 14, the desorbing solution has a salt concentration of 0.5 M or less (ex. 3, for example).

With regard to claim 15 and 16, Mullis teaches a method wherein adsorption and desorption of the nucleic acid is performed by use of a unit for isolation and purification comprising (a) a membrane of the organic macromolecule; (b) a container having at least two openings and containing the membrane; and (c) a differential pressure generator connected to one opening of the container. Specifically, Mullis teaches an example wherein the adsorption and desorption of the nucleic acid is performed within a vacuum-filtration device which is a container with at least two openings and which contained a cellulose acetate membrane filter (ex. 4, for example). Further, the vacuum filtration device inherently would be connected to a differential pressure generator (i.e. the vacuum) that is connected to an opening of the device.

Mullis does not expressly teach surface saponification of cellulose acetate membranes.

Tuccelli provides a supporting disclosure that teaches cellulosic membranes having a surface saponified ultrafiltration layer (col. 3; ex. 1-3, for example). They expressly teach a membrane with a 11  $\mu\text{m}$  saponified layer of cellulose (col. 6, lines 1-10, for example).

With regard to claim 4, Tuccelli teaches surface-saponified triacetylcellulose (col. 3, lines 55-65, for example).

With regard to claims 5 and 6, Tuccelli teaches saponification rates of 5% or higher (col. 5, lines 40-45, for example).

With regard to claim 7, Tuccelli teaches porous cellulose acetate membranes (col. 3, lines 40-45, for example).

Tuccelli further teaches that their cellulose membranes are resistant to high-back pressures as compared to those cellulose membrane of the prior art (col. 3, lines 30-35; table 1, for example)

It would have been *prima facie* obvious for a practitioner of ordinary skill in the art at the time of invention to incorporate the membranes of Tuccelli into the methods of Mullis since the membranes of Tuccelli are resistant to high-back pressures, thus arriving at the claimed invention.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not persuasive. Applicant first argues that Tuccelli only mentions the processing of protein containing solutions with their membranes. This argument is not persuasive because Mullis teaches the separation and purification of nucleic acid through the use of cellulose acetate membranes.

Applicant next argues, as understood by the Examiner, that a skilled artisan would not expect surfaces typically used with DNA to be generally adaptable to the

separation of proteins. This argument is not persuasive because, as set forth above, Mullis teaches the separation and purification of nucleic acid through the use of cellulose acetate membranes. Thus, a skilled artisan would have expected the saponified cellulose acetate membranes of Tuccelli useful in the separation and purification of nucleic acid.

A skilled artisan at the time of invention would have seen the benefit of strengthening filtration membranes to resist physical damage.

Thus, the rejections are maintained.

**3. Claims 10 and 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis (U.S. 5,187,083) as evidenced by GE Osmonics (<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes") in view of Bryk et al. ("Porous structure of cellulose acetate ultrafiltration membranes of various degrees of saponification" Polymer Science U.S.S.R., Volume 32, Issue 7, 1990, Pages 1401-1409) as applied to claims 1, 2, 7, 9, 12, and 14-16 above, or Tuccelli et al. (U.S. 5,522,991) as applied to claims 1, 2, 4-7, 9, 12, and 14-16 above, and in further view of Kuroita et al. (U.S. 5,990,302).**

The methods of the previously applied reference(s) have been outlined in the above rejections. Mullis teaches using "typical" procedures for obtaining DNA from samples (col. 5, lines 10-30, for example), however, does not expressly disclose a

reagent set comprising a water-soluble organic solvent, guanidine salt, a surfactant, and a protease.

Kuroita teaches that target nucleic acid molecules are released from cells by treatment with a reagent set comprising a water-soluble organic solvent, guanidine salt, a surfactant, and a protease (col. 7, line 50-col. 8, line 15, for example).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by Mullis so as to have utilized a lysis buffer that included reagents that are typically considered lysis agents for the release of nucleic acids from sample cells. One would have been motivated by the teachings of Mullis to use any such typical methodologies for obtaining lysis solutions, such as those exemplified by the teachings of Kuroita. It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to practice the methods as claimed.

#### **Response to Arguments**

Please see responses set forth above.

**4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis (U.S. 5,187,083) as evidenced by GE Osmonics (<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes") in further view of Heath et al. (WO 99/13976).**

The methods of the previously applied references have been outlined in the above rejections. The previously applied references do not expressly teach the sequence of steps required in claims 17 and 18 wherein fluids are brought into contact with the membrane by inserting one opening of a unit for isolation and purification into a fluid (first sample, second washing buffer, third desorbing solution), creating a reduced pressure in a container by a differential pressure generator to suck the fluid into the chamber and into contact with the hydroxyl group, and creating an increased pressure within the chamber which results in discharge of the fluid from the chamber. Claim 17 requires the repetition of these steps for three different fluids, while claim 18 requires the repetition of these steps for only the sample and the desorbing solution.

Heath discloses methods for isolation of nucleic acid from samples and teaches automated steps of loading a sample into a container with at least two openings (pg. 7, lines 11-12, for example), loading a wash into the container (pg. 7, lines 13-17, for example), and loading desorbing buffer (referred to as elution buffer) into the container (pg. 7, lines 18-23, for example). Heath discloses the use of vacuum pumps for the movement of solutions into and out of the isolation chamber (pg. 8, lines 6-14; 21-22, for example). Heath specifically teaches that methods in which the sample is loaded via aspiration which occurs via the insertion of the opening of the chamber into the sample and the application of negative pressure to suck the sample into the chamber (p. 10, exemplified pg. 23, for example). Further, Heath teaches methods in which the gases are pumped into the chamber which increases pressure in the chamber and

It would have been *prima facie* obvious to one of ordinary skill in the art to have applied the sample processing methodologies taught by Heath to the methods taught by applied references since Heath suggests such methodologies for automation of sample processing.

### **Response to Arguments**

Please see responses set forth above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**1. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: 1) claims 1-18 of copending Application 10/209,336; 2) claims 1-2 of copending Application 10/305,110; 3) claims 1-18 of copending Application No. 10/621,412; 4)**



Art Unit: 1637

**claims 1-20 of copending Application No. 10/621,715, and; 5) claims 1-35 of copending Application 10/975,469 in view of Mullis (U.S. 5,187,083) as evidenced by GE Osmonics**  
**(<http://www.osmolabstore.com/OsmoLabPage.dll?BuildPage&1&1&897>, "GE CA (Cellulose Acetate) Membranes").**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is drawn to a method for separating and purifying a nucleic acid wherein each method encompasses the same general inventive concept of adsorbing and desorbing a nucleic acid onto an surface saponified acetylcellulose solid phase.

It would have been *prima facie* obvious to incorporate a membrane (i.e. solid phase) with the broad thickness range of the claimed invention. The inclusion of this limitation is well within the range of ordinary skill in the art as demonstrated, for example, by Mullis (ex. 4, for example).

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

### **Response to Arguments**

Applicant's arguments have been fully considered but are not persuasive. A "provisional" ODP rejection is not the only rejection remaining in the instant application. Thus, the ODP rejections have been maintained.

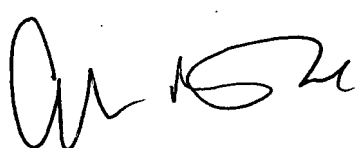
### ***Conclusion***

**Claims 1, 2, and 4-18 are rejected. No claims allowed.**

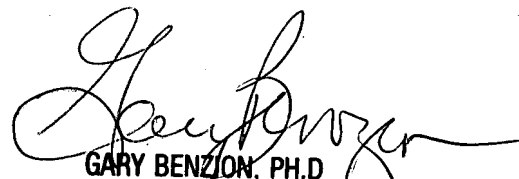
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 1/22/07

Christopher M. Babic  
Patent Examiner  
AU 1637

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600